IMPROVING ORGANIZATIONAL PERFORMANCE

VA PUGET SOUND **MEMORANDUM PI–01**
HEALTH CARE SYSTEM **JANUARY 2013**

SUBJECT: PATIENT SAFETY IMPROVEMENT PROCESSES

1. **EXECUTIVE SUMMARY**: This policy outlines the requirements for VA Puget Sound employees about reporting of patient safety events and the basis of VA Puget Sound Patient Safety Program. This policy is aligned with The Joint Commission (TJC) standards and Veterans Health Administration (VHA) National Patient Safety Improvement Handbook 1050.1 (March 2011). This revision updates the November 2009 Medical Center Memorandum (MCM) PI-01.

2. **POLICY:**

   a. It is the responsibility of all VA Puget Sound employees and practitioners to report adverse events and potential adverse events (see Attachment A) using a sanctioned reporting mechanism.

   b. The aim of the VA Puget Sound Patient Safety Program is the prevention of harm to patients during the delivery of health care. The Patient Safety Program is charged with exploring system vulnerabilities which pose risk of harm to patients and ensuring the implementation of systems level actions to reduce this risk.

3. **PROCEDURES:**

   a. All employees will report adverse events and/or close calls (see Attachment A) using a sanctioned mechanism. Employees who regularly report events as part of their primary role (for example, infection surveillance) are expected to use the electronic incident reporting system. Reporting is confidential and protected under 38 US Code §5705. The Patient Safety Hotline (6-SAFE from internal VA phones) is available for anonymous reporting. The following reporting mechanisms are authorized:

      1) Patient Incident Report (PIR) system in VistA,

      2) Voicemail left on the Patient Safety Hotline (6-SAFE from internal VA phones),

      3) Face to face or telephonic communication with Patient Safety Program staff,

      4) Email message, encrypted per VA Puget Sound policy, to Patient Safety Program staff, and

      5) Pre-developed automatic notification triggered by clinical documentation (for example, falls occurring in home care settings).

   b. In addition to reporting by employees, patient safety events may be identified by Patient Safety Program staff and others during occurrence screens, record review for quality assurance, peer review or utilization management, mortality and morbidity reviews, and other processes.

   c. Staff and supervisors will notify the Patient Safety Program staff immediately upon discovery of any Sentinel Event as defined by TJC and VHA Handbook (see Attachment A).

d. Any actual event related to patient care (for example, fall, wrong site surgery) will be recorded in the medical record as appropriate to the case, but the submission of an incident report should not be documented in the medical record. Guidance about documentation in the medical record is available from the Quality Improvement (QI), Risk Management, and/or Patient Safety staff.

e. Patient Safety Program staff will review, score and enter actual and potential patient safety events into the SPOT database as outlined in the VHA Handbook. The investigation into these events about systems issues will be completed by the Patient Safety Program staff or, alternatively, may be delegated to others (for example, a subject matter expert).

f. Licensed independent practitioners will disclose medical errors consistent with MCM RI-17 Disclosure of Adverse Events to Patients. *Disclosure to patients (both clinical and institutional) is overseen by the Risk Management program and questions about disclosure may be directed to Risk Management*.

g. Events involving criminal activity or intentionally unsafe acts are out of the scope of the Patient Safety Program and will be referred for administrative review, consistent with the VHA Handbook.

h. Adverse Drug Reactions (ADRs) will be reported through the medical center ADR reporting program. Patient Safety will work together with the ADR coordinator and quality improvement to review ADR events resulting in significant patient harm and/or linked to system level vulnerabilities.

i. Employees will report patient safety events likely to result in adverse publicity to VA Puget Sound or the VHA as soon as possible through one of the reporting mechanisms outlined in section 3.a. above.

4. **RESPONSIBILITES:**

a. The Director is responsible for:

1) Chartering Root Cause Analyses (RCAs) based on the recommendation of the Patient Safety Program Director or designee, and

2) Ensuring that the National Center for Patient Safety (NCPS) is notified when an issue is detected that could affect other VHA facilities and/or may require the development of a national-level Alert or Advisory.

b. The Director, the Deputy Director, the Chief of Staff, the Assistant Director, and the Associate Director for Patient Care Services are responsible for:

1) Supporting a culture of safety,

2) Facilitating an integrated Patient Safety Program,

3) Ensuring that patient safety issues are given a high priority when processes, functions, environments of care, or services are designed or redesigned, and

4) Acting according to 38 U.S.C. §5705, which affords the Patient Safety Program protection as a medical quality assurance program.

c. The Director of the Patient Safety Program is responsible for coordinating the daily operation of the Patient Safety Program and ensuring compliance with the VHA National Patient Safety Improvement Handbook 1050.1. A complete list of responsibilities is included in the Handbook. Some of these responsibilities include:

1) Development of the Patient Safety Program, focusing on topics identified through data analysis and risk assessment by the Patient Safety Program staff, the Patient Safety Committee, and Facility Leadership,

2) Overseeing the identification, reporting, systems-level investigation, analysis, and follow-up of patient safety events reported to the Patient Safety Program,

3) Referring events for RCA, ensuring thorough, credible and timely RCAs, and monitoring RCA action item completion and outcome measures,

4) Facilitating Proactive Risk Assessments (see Attachment A) as required by TJC and NCPS,

5) Collaborating with QI, Risk Management, Systems Redesign, Utilization Management, Compliance, IntegratedEthics, clinical and non clinical services (for example, Safety) to facilitate and integrate program activities and organizational improvement,

6) Maintaining the integrity of the Patient Safety Program through adherence to confidentiality and protection of documents as outlined by 38 U.S.C. §5705 and the VHA Handbook,

7) Reviewing VA Patient Safety Alerts and Advisories and monitoring completion of required actions and applicable recommendations, and

8) Reviewing TJC Sentinel Event Alerts, engaging subject matter experts in the review, and recommending actions based on the recommendations. This responsibility may be delegated when appropriate.

d. Service Line Leaders, managers, and supervisors are responsible for:

1) Promoting a culture of safety by providing a supportive environment for reporting actual and potential adverse events,

2) Coaching and educating staff regarding the Patient Safety Program and processes, including reporting of events, and

3) Acting according to 38 U.S.C. §5705, which affords the Patient Safety Program protection as a medical quality assurance program.

e. All facility staff are responsible for:

1) Reporting actual and potential patient safety events to the Patient Safety Program, and

2) Taking immediate action to prevent the risk of additional harm, when it is possible to do so.

5. **REFERENCES:**

   a. VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook (March 2011).

   b. Joint Commission Comprehensive Accreditation Manuals for Hospital, Long Term Care, Home Care, and Behavioral Health programs.

   c. VAPSHCS Memorandum TX-17, Adverse Drug Reactions/Drug Allergies

   d. VAPSHCS Memorandum RI-17 Disclosure of Adverse Events to Patients

6. **RESCISSION:** Memorandum PI-01, November 2009.

7. **FOLLOW UP RESPONSIBILITY:** Director, Patient Safety Program

8. **EXPIRATION:** January 2016

JOHN E. PATRICK
Interim Director

Attachment A: Patient Safety Definitions

PATIENT SAFETY TERMS, DEFINITIONS, AND TOOLS

Administrative Investigation (AI) – An investigation that involves testimony under oath. This type of investigation may be utilized following an alleged intentional unsafe act or criminal act, and the resultant documents are not protected from disclosure.

Adverse Drug Reaction – Any untoward noxious reaction associated with drug use at any dose. An adverse drug reaction may result from administration of non-prescription, prescription, or investigational/research drugs; and includes events occurring due to drug allergy, drug withdrawal, and drug overdose (whether accidental or intentional) and significant failure of expected pharmacological action. Reactions to medication administration that do not require discontinuation of the drug or treatment of the reaction are not considered adverse drug reactions; they are considered minor side effects.

Adverse Event – An untoward incident, therapeutic misadventure, iatrogenic injury or other adverse occurrence directly associated with care or services provided within the jurisdiction of the health care system. Adverse events may result from acts of commission or omission, e.g., administration of the wrong medication or failure to make a timely diagnosis or institute the appropriate therapeutic intervention. All adverse events require review, documentation, and reporting, according to the Patient Safety Improvement Handbook.

Close Call – An event that could have resulted in an accident, injury, or illness, but did not, either by chance or through timely intervention. Such events have also been called “near miss” incidents. Close calls are opportunities for learning and afford the chance to develop prevention strategies and actions. They receive the same level of scrutiny as adverse events that result in actual injury. Close calls may also include potential adverse drug events, not included in the ADR reporting, monitoring and tracking program but are valuable sources of information.

Intentionally Unsafe Act – Any event pertaining to a patient that results from a criminal act, a purposefully unsafe act, an act related to alcohol or substance abuse by an impaired provider/staff, or an event involving alleged or suspected patient abuse of any kind.

Medical Error – A failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Medical errors can include problems in practices, products, procedures and systems.

Patient Incident Reporting (PIR) System – A local VISTA-based system used to electronically transmit, store, and sort information about certain types of adverse events involving patients.

Patient Safety – Refers to ensuring freedom from accidental or inadvertent injury during health care processes.

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Prospective Risk Assessment – A method of evaluating product or processes to identify system vulnerabilities, and their associated corrective actions before adverse events. Examples include HFMEA (Healthcare Failure Mode Effect Analysis).

Protected Peer Review for Quality Management – Defined to include critical review of care performed by a peer and/or group of peers. Protected peer review is outlined by VHA Directive 2008-004 “Peer Review for Quality Management” and by local medical center policy.

Root Cause Analysis (RCA) – An interdisciplinary team process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls. The analysis focuses primarily on systems and processes rather than individual performance.

Sentinel Event – An unexpected occurrence involving death, serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function (permanent loss of function means sensory, motor, physiologic or intellectual impairment unrelated to the patient's disease process). "Risk thereof," includes any process variation for which a recurrence would carry significant chance of serious adverse outcome. The Joint Commission has developed and published the definition. Sentinel events require immediate investigation and response. Root cause analysis is one method of investigation and response.

SPOT – An electronic database of the VHA National Center for Patient Safety (NCPS) that tracks all RCAs completed with the VHA system as well as patient incidents entered by Patient Safety staff.